

TAMOXIFEN CITRATE- tamoxifen citrate tablet, film coated
Zydus Lifesciences Limited

Tamoxifen Citrate Tablets, USP

SPL MEDGUIDE

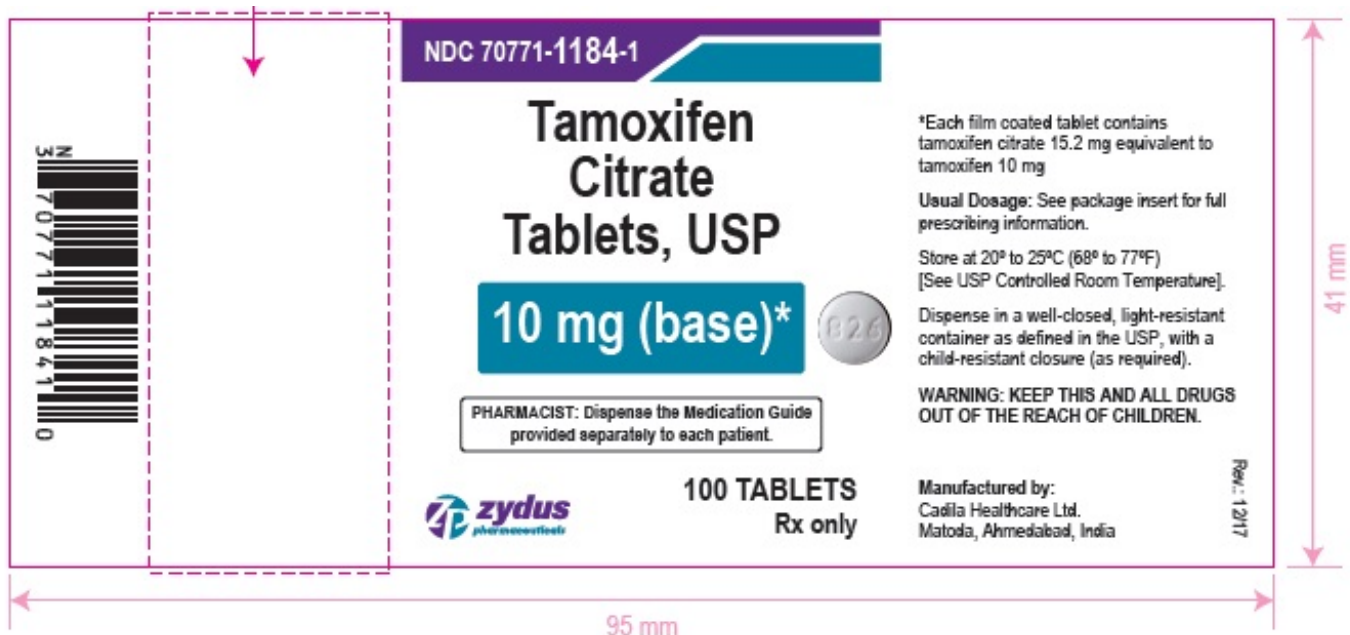
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1184-1 in bottle of 100 tablets

Tamoxifen Citrate Tablets USP, 10 mg

Rx Only

100 tablets



NDC 70771-1185-1 in bottle of 100 tablets

Tamoxifen Citrate Tablets USP, 20 mg

Rx Only

100 tablets



TAMOXIFEN CITRATE

tamoxifen citrate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1184
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TAMOXIFEN CITRATE (UNII: 7FRV7310N6) (TAMOXIFEN - UNII:094ZI81Y45)	TAMOXIFEN	10 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	826
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1184-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
2	NDC:70771-1184-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
3	NDC:70771-1184-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
4	NDC:70771-1184-8	180 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206694	01/03/2018	

TAMOXIFEN CITRATE

tamoxifen citrate tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1185
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TAMOXIFEN CITRATE (UNII: 7FRV7310N6) (TAMOXIFEN - UNII:094ZI81Y45)	TAMOXIFEN	20 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	9mm

Flavor		Imprint Code	827	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1185-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
2	NDC:70771-1185-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
3	NDC:70771-1185-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
4	NDC:70771-1185-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
5	NDC:70771-1185-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2018	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA206694	01/03/2018		

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1184, 70771-1185) , MANUFACTURE(70771-1184, 70771-1185)

Revised: 9/2023

Zydus Lifesciences Limited